Remarks

Claims 18-28 are pending in this application after entry of the amendment above. Claims 18, 19, 22, 24 and 26 have been amended. New claim 28 has been added. No new matter has been added. These amendments do not narrow the scope of protection nor have they been made to overcome the pending rejections. Rather, they have merely been made to more particularly point out what Applicant believes to be his invention.

The Examiner has rejected claims 18-27 under 35 USC § 103(a) as being unpatentable over Litt et al or Bernstein et al. or Britt et al. in view of taking of Official Notice and Applicant's Own Admission. Applicant respectfully traverses this rejection.

Applicant provides the following background information to assist the Examiner in understanding the subject matter of the claims. The claims, however, should not be limited based on these statements.

There are many different types of batch manufacturing processes including pharmaceutical, biopharmaceutical, dairy, food, beverage, nutraceutical, cosmetics, specialty chemical, etc. All batch processes are characterized by a basic process or unit operation sequence in which the respective manufacturing equipment is utilized for varying durations and according to various cycling patterns. In addition, batch process trains that consist of a sequence of unit operation equipment tend to be dedicated to a given product during a production campaign until that campaign has ended. This batch campaign segregation helps reduce the risk of adulterating the product through the cross contamination that might result from sharing the same equipment between different batch processes without adequate turnaround activities such as cleaning, etc. between

campaigns. Many batch processes involve the processing of liquids or powdered or granular solids, which are transferred by pumping or conveying mechanisms from one unit operation to another. Therefore the unit operation equipment that comprise batch processes also tend to be "hard piped" together, which also promotes batch process train and campaign segregation.

The claimed invention includes a number of operations, which will be described briefly below. This is only an example. The claims should not be limited by this example. The method first identifies a high level process step of a biopharmaceutical production process. The process step includes a plurality of unit operations. Thus, for example, there may be a consecutive sequence of unit operations A, B and C. These unit operations each include one or more tasks necessary to complete the respective unit operation. Further, a scheduling cycle value is defined, for example, for each unit operation individually (claim 18), a cluster of unit operations A, B, and C (aka cycles per batch)(claim 28), or cycles per process (claim 28). For example, a cluster of unit operations or an individual unit operation may need to be executed multiple iterations during a manufacturing process. The number of iterations a given cycle is to be executed is one type of scheduling cycle. The time between the start of respective cycle iterations (offset) is another type of scheduling cycle value. (Note: these are just examples of scheduling cycle values; there are others contemplated to be within the scope of the claimed invention.) Finally, the process is scheduled to generate a process time line that takes into account the scheduling cycle value(s). The process time line identifies initiation and completion times for each of the tasks for each unit operation in the biopharmaceutical process.

Litt et al., Bernstein et al. and Britt et al fail to teach or suggest, *inter alia*, the generation of a process time line based on schedule cycle values. The Examiner has merely quoted portions of the cited art, but has failed to particularly point out where the art teaches and suggests each feature of the claimed invention, and in particular the generation of a process time line. The Examiner is respectfully requested to point out with particularity where the art teaches the above-cited features should he determine that the clams are not allowable over the art of record.

Further, a biopharmaceutical batch process may require a dozen or more unique solution formulations that each need to be prepared from several reagents, filtered and temperature conditioned prior to their use in a batch process. In a sense, each of these solution preparation operations is a batch process that is required to support the primary batch process of producing a biopharmaceutical product from genetically engineered cells and purifying the product that the cells make. The preparation and cleaning of equipment between use cycles can also be considered a supporting batch process of its own, which is dependent on the primary process time. Also, performing quality control sampling and testing can also be considered a supporting batch process of its own. The claimed invention addresses each of these issues in scheduling an overall biopharmaceutical process as recited in claims 18-28.

The art applied by the examiner also does not make the above distinctions between primary process unit operations and process support operations. In particular, the art fails to teach or suggest scheduling solution preparation to generate a solution preparation time line (claim 19), scheduling of equipment preparation to generate an equipment preparation time line (claim22), scheduling equipment maintenance to

generate an equipment maintenance time line (claim 24) or scheduling of quality control sampling and testing to generate a quality control time line (claim 26), which are all in addition to the generation of the process time line generated in independent claim 18. The Examiner is respectfully requested to point out with particularity where the art teaches the above-cited features should he determine that the clams are not allowable over the art of record.

The Examiner takes Official Notice that one of ordinary skill in the art at the time of the invention would recognize and choose the appropriate process and control variables necessary for the particular field based on the fact that Applicant's invention can be applied to other types of batch processes other than biopharmaceutical. Some batch processes require relatively little infrastructure to support the basic process unit operations presented in a process train, while other batch processes require extensive support infrastructure in multiple levels that are hierarchically related (nested). Of the above batch process types, biopharmaceutical is regarded as requiring the most complex support infrastructure, including solution preparation, storage and distribution, equipment preparation and maintenance, quality control, etc. Thus, Applicant disagrees with the Examiner that it would be obvious to take a batch processing technique in another field and apply it to a biopharmaceutical batch process. The fact that Applicant's invention can be applied to processes other than biopharmaceutical does not mean that prior techniques in fields different from biopharmaceutical will work in a biopharmaceutical environment. The Examiner's Official Notice is therefore misplaced.

Conclusion

Prompt and favorable consideration of this amendment and reply is respectfully requested. Applicant believes the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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Date: November 15, 2004

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